National Institute of Neurological Disorders and Stroke

CDC — Centers for Disease Control and Prevention
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Myalgic Encephalomyelitis/
Chronic Fatigue Syndrome (ME/CFS)
Common Data Elements

Development Overview

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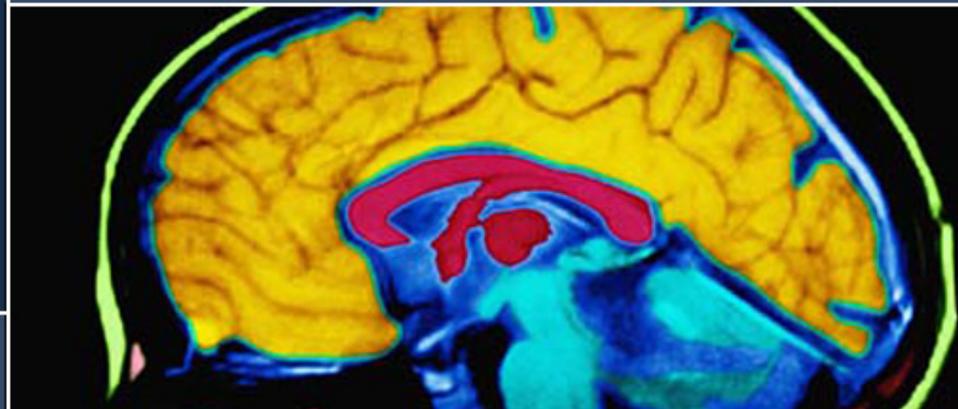
Overview - Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS) Recommendations

- ✓ Background
- ✓ Objectives
- ✓ Terminology
- ✓ Current Status
- ✓ CDE Development Process

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PROJECT OVERVIEW   CDE SEARCH   CRF SEARCH   FORM BUILDER   CONTACT
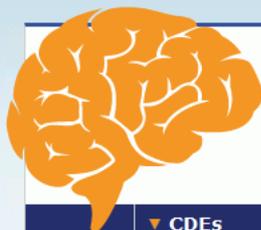
NINDS Common Data Elements
Harmonizing Information. Streamlining Research.

▼ CDEs   ▼ Tools   ▼ Learn

Streamline Your Neuroscience Clinical Research using content standards that enable clinical investigators to systematically collect, analyze, and share data across the research community.

The NINDS strongly encourages researchers who receive funding from the Institute to ensure their data collection is compatible with these common data elements (CDEs). Learn more about the CDE Project.

Launch Your Own Studies Faster
▶ Case report form modules
▶ Standardized data element definitions
▶ Instrument recommendations

Incorporate CDEs Into Systems
▶ Search for current CDEs
▶ Download CDE metadata
▶ Download Case Report Forms

Learn About the CDE Project
▶ Project overview and background
▶ Meetings and Presentations
▶ Collaboration with developers around the world

CDEs Now Available	CDEs Under Review	CDEs in Development

General (CDEs that cross diseases)

Amyotrophic Lateral Sclerosis

Cerebral Palsy

Chiari I Malformation

Epilepsy

Friedreich's Ataxia

Headache

Huntington's Disease

Mitochondrial Disease

Multiple Sclerosis

Privacy Statement | NeuroQOL | NIH Toolbox | PROMIS

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Harmonizing information. Streamlining research.

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Turning Discovery Into Health

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Welcome to the NINDS/CDC CDE PROJECT

What is the CDE Project?

- NINDS/CDC initiated the development of Common Data Elements (CDEs) as part of a project to develop data standards for funded clinical research in neuroscience.

- The CDEs are content standards that can be applied to various data collection models and are intended to be **dynamic** and **may evolve** over time.

- CDEs are **not** a database.

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What are the goals of the CDE Project?

- Develop **common definitions** of each data element and **standardize** case report forms (CRF) and other instruments

- Help investigators conduct clinical research through the development of these uniform formats by which clinical data can be **systematically collected, analyzed** and **shared** across the research community

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What are the objectives of the CDE Project?

- Identify CDEs used in clinical research
  - (age, gender, race, etc.)

- Present data elements in a standard format available to all

- Identify common meanings of each data element
  - (including permissible values, range checks, etc.)

- Standardize CRFs, when needed, and instruments

- Provide information to researchers for clinical data collection and sharing

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Motivation & Overall Impact of the NINDS/CDC CDE Project

Motivation	**Impact**
Trials were costing too much: no one believed in re-use of CRFs	➢ Reduce time/cost to develop data collection tools
Trials were taking too long and costing too much to get up and going	➢ Reduce study start-up time and cost of overall trial
Data quality varied, no standards	➢ Improve data quality
Data collection was not consistent	➢ Facilitate collection of data
Comparisons of data between studies was not possible	➢ Facilitate data sharing/comparisons between studies and meta-analyses

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What is a CDE?

- CDEs are a logical unit of data pertaining to one kind of information

  - Name

  - Precise Definition

  - Permissible Values (if applicable)

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What is a CDE:

- Standardized question and potential answer
- Allows for consistent collection and sharing of data
- Semantic value (the CDE name) with clear definitions and permissible values

Examples:

CDE Name: "Type of TBI"

Definition: "Broad classification of the type of traumatic brain injury experienced by participant/subject"

Data Type: "Alphanumeric "

Input Restrictions: "multiple Pre-Defined Values Selected"

Case Report Form:

Type, Place, Cause and Mechanism of Injury

[Study Name/ID pre-filled]   Site Name:

                                              Subject ID:

Type of TBI* (Choose one)

☐ Closed   ☐ Blast   ☐ Penetrating   ☐ Crush

CDE ID	CDE Name	Variable Name	Definition / Description	Question Text	Permissible Value
C05420	TBI type	TBITyp	Broad classification of the type of traumatic brain injury experienced by participant/subject	Type of TBI	Closed;Penetrating;Blast;Crush;Unknown;

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CDE Details include but are not limited to…

- Metadata name (CDE name)
- Definition
- Example Question Text
- Permissible Values/Permissible Value descriptions
- Data Type
- Instructions
- References
- Population
- Classification
- Input Restriction
- Size
- Min Value and Max Value
- Measurement type

Developing New Recommendations for Clinical Research CDEs

- **Working Groups and NINDS/CDC CDE Team work together to develop disease specific research CDEs/CRFs:**

  - Collect and review data report forms from disease-specific and other outcomes databases

    - Registries, clinical research projects, etc.

  - Assess what can be shared between disorders from within the NINDS CDE website or other CDE-type activities

    - The greater the overlap and reuse of CDEs, the greater impact on future data-mining and data sharing

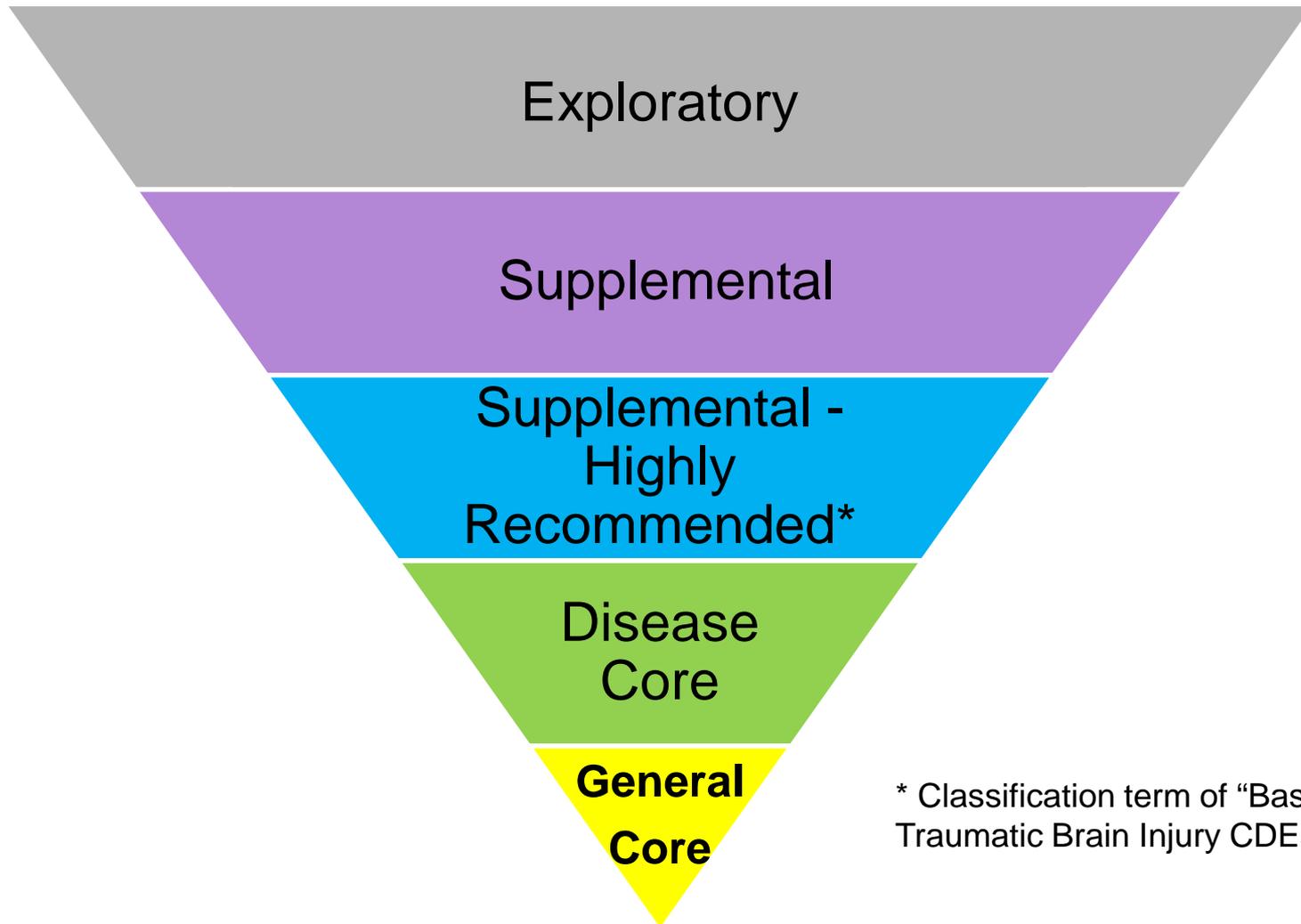 - Identify appropriate outcome measures

Initial CDE Development Process

Development Step	Typical Timeframe
NINDS/CDC invites Working Group (WG) members and WG Chair(s)	2-4 weeks
NINDS/CDC works with Chair(s) to divide WG into Subgroups and to nominate Subgroup Chairs	2-4 weeks
Introductory meeting of WG at national/international conference or via Web conference*	1-2 hours
Subgroups meet every 3-5 weeks via conference call to develop CDEs for assigned areas	6-9 months
Internal WG Review of all Subgroups' CDEs	1 month
Subgroups revise CDEs based on feedback from Internal WG Review	1-2 months
Public Review of WG's CDEs	6-8 weeks
Subgroups revise CDEs based on feedback from Public Review	1 month
Post Version 1.0 of CDEs on Web site	2-4 weeks
TOTAL	**12-18 months**

If the WG does not meet in-person at the beginning of the process the NINDS/CDC schedules the in-person meeting to coincide with a large meeting/conference later in the process.

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CDE Terminology – Classifications

Exploratory

Supplemental

Supplemental - Highly Recommended*

Disease Core

General Core

* Classification term of "Basic" used for Traumatic Brain Injury CDEs

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Example of a Case Report Form

Electrocardiogram (ECG)

1) Date and time of ECG: yyyy/mm/dd   ☐ am ☐ pm ☐ 24-hour clock

2) Ventricular rate / Heart rate: beats/min

3) PR interval*: msec

4) QRS duration*: msec

5) QT interval*: msec

6) QTc interval: msec

7) QRS axis:

8) ECG results: (Choose one)
☐ Normal
☐ Abnormal, not clinically significant
☐ Abnormal, clinically significant
☐ Unable to evaluate

9) Heart rhythm: ☐ Normal sinus rhythm

   If not normal:
   ☐ Sinus tachycardia
   ☐ Sinus bradycardia

   ☐ Atrial arrhythmia, specify type: ☐ Atrial fibrillation   ☐ Atrial flutter ☐ Other
   ☐ Ventricular arrhythmia, specify type: ☐ Ventricular fibrillation ☐ Ventricular tachycardia
   ☐ Other
   ☐ Other, specify:

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Example of an Instrument Recommendation

NINDS CDE Notice of Copyright
Borg Rating of Perceived Exertion (RPE) Scale

Availability:	Copyrighted Gunnar Borg, 1970, 1985, 1994, 1998 Information about this instrument can be found at Borg Rating of Perceived Exertion (RPE) Scale Instrument Link
Classification:	**Supplemental – Highly Recommended:** Exercise Studies in Mitochondrial Disease **Exploratory:** Spinal Cord Injury (SCI) and SCI-Pediatric (age 10 and over)
Short Description of Instrument:	**Construct measured:** Perceived exertion **Generic vs. disease specific:** Generic **Intended respondent:** Participant
Comments/Special instructions:	**Scoring:** Participants are asked to rate their perception of exertion during physical activity. The severity is measured on either the original scale of 6–20 ("6"meaning "no exertion at all" and "20" meaning "maximal exertion"),or the modified scale of 0–10. **Original 6-20 Scale:** Rating:Perceived Exertion 6:No Exertion at all 7 7.5:Extremely light 8 9:Very light 10 11:Light 12 13:Somewhat hard 14 15:Hard (heavy) 16 17:Very hard 18

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NINDS CDE Disease Areas – over 13,000 CDEs & 800 Instruments

General CDEs

Chiari I Malformation (new)

Cerebral palsy (new)

Epilepsy*

Headache

Mitochondrial disorders*

Movement disorders
- Parkinson's disease
- Huntington's disease

Multiple sclerosis

Spinal cord injury (SCI)*

Stroke*
- Unruptured Cerebral Aneurysms and Subarachnoid hemorrhage (new)

Traumatic brain injury*
- Sports-Related Concussion (new)

Neuromuscular disorders*
- Amyotrophic lateral sclerosis
- Friedreich's ataxia
- Muscular dystrophies
  - *Congenital, Duchenne/Becker, Facioscapulohumeral, Myotonic*
- Myasthenia gravis
- Spinal muscular atrophy

Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS) (under review)

Biomechanical Sensors in Traumatic Brain Injury (under review)

*Includes pediatric-specific recommendations

NINDS/CDC Vision for CDEs

- ME/CFS studies would use the CDEs and research progress will be accelerated
  - NIH-funded research studies use CDEs or are CDE-compatible – it is part of FOA and Terms of Award
  - New investigators can build on consensus data elements
  - Start-up of multi-center and international clinical research efforts will be facilitated
- All types of clinical research can use part of the CDEs
  - Observational clinical studies can be linked to trial datasets
  - All human subject grantees are asked to consider using CDEs

Submitting Feedback on CDEs

- Feedback from users is key to ensuring project goals are met

    - Submit feedback form on NINDS CDE website
    www.commondataelements.ninds.nih.gov

Timeline of ME/CFS CDEs

- January 23 and February 13, 2017
  - Orientation teleconferences
- February 2017
  - All members split into subgroups
  - Chairs for each Subgroup designated
- March – October 2017
  - Working Group members work on their respective subgroup assignments
  - Monthly meetings are scheduled for each subgroup
  - Main contact: NINDSCDE@emmes.com
- October – November 2017
  - Internal review
- December 2017– January 2018
  - Public review
- February 2018
  - Posting of ME/CFS CDEs on the NINDS CDE Website

Accessing the NINDS/CDC CDEs

NINDS Common Data Elements Website

www.commondataelements.ninds.nih.gov

Submitting Feedback on CDEs

Feedback form on NINDS CDE website
https://www.commondataelements.ninds.nih.gov/ProjReview.aspx

For more information on the NINDS/CDC CDEs, please contact: NINDSCDE@emmes.com